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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/306,780	TAKEMURA ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 3, 2003 has been entered.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) the rejection of claims 33-35 under 35 U.S.C. 102(b) as being anticipated by Thomas et al., (US Patent 4,749,647); and
b) the rejection of claims 33-40 under 35 U.S.C. 112, first paragraph.

New Grounds Of Rejection
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 24 and 33 are conflicting. Although the conflicting claims are not identical, they are not patentably distinct from each other because even through the preamble of claim 25 is drawn to an agglutination

immunoassay for assaying an antibody, the steps within the immunoassay recite the same steps as those seen claim 33. Likewise, dependant claims 26-32 and 34-40 are all drawn to identical limitations on the nucleic acid bound polypeptide. Therefore, the claims are duplicative. Thus, the method steps are not patentably distinct and are thereby rejected.

4. The preamble of the claim 33 is drawn to a method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay comprising a preparation step; a contact step and a measurement step. There is no correlation step that correlates increasing immunological reactivity of a polypeptide in an agglutination immunoassay to measuring agglutination images. The claims do not teach steps that recite how to increase the immunological reactivity as recited by the preamble of the claim. There is no correlation between the agglutination and determining an increase of immunological reactivity of a polypeptide. Therefore, the claims are rejected because they fail to recite necessary method steps. The goal of the preamble is not commensurate with the steps of the method that are drawn to increasing immunological reactivity of a polypeptide in an agglutination immunoassay.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 25-27 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al., (US Patent 4,749,647) in view of Gibbons (US Patent 4,829,011).

Thomas et al., (US Patent 4,749,647) teach methods for a general method for the detection and measurement of analytes in a sample (col. 6 lines 40-43). Interactions or associations between the different analytes are amenable to detection and measurement using different sets of recognition pairs (col. 8 lines 55-59). For example, specific DNA/protein interaction can be assayed under appropriate conditions using a labeled antibody to the protein analyte and a labeled probe for the DNA analyte, one of the two labels being a monomer and the other, a reporter (col. 8 lines 60-65). In general, such determination requires cross-linking of the protein(s) to the nucleic acid and fragmentation of the nucleic acid prior to the assay (col. 8 lines 65-68). Thomas et al., teach immunoassays of the present invention can be performed in any of several configurations (col. 9 lines 3-5). Specific binding to polymer particles after incubation would allow binding to occur; washing of the particles if necessary can occur, however measurement of the amount of reporter associated with the particle can occur or the particles can be separated from solution (col. 9 lines 50-63). Example V teaches analyte association assays including synthesis and monomerization of analyte detecting sequences. While example V-E teach an assay for p19 protein binding to Rous Sarcoma Virus-RNA (RSV-RNA). This would be a nucleic acid bound polypeptide. The inventors teach using a fluoresceinated anti-p19 antibody to detect the mixture (col. 43 lines 31-32). Thus the antigen is contacted with an antibody. Under this system,

fluorescence is incorporated into the polymer particles (col. 43 lines 40-41). Two controls were run, which showed that there was substantially less incorporation of fluorescence into the polymer particles, indicating that both p19 protein and RSV-RNA are required for incorporation of the reporter in to the polymer (col. 43 lines 46-49).

Gibbons teaches a method of detecting the presence or amount of agglutination of particles in a reaction medium (col. 2 lines 15-24). The method steps comprise forming a reaction medium containing (1) a sample; (2) a plurality of particles having a binding pair member bound to their surfaces; and (3) a monovalent complementary partner to said binding pair member to which is attached an analyte mimic or analyte binding partner; and detecting the presence of agglutination of said particles in the reaction medium (col. 2 lines 15-24). Examples of such binding pairs include antigens and antibodies and complementary nucleic acid strands (col. 5 lines 38-42). Agglutination assays do not require expensive detection equipment, can be visually read agglutination, usually qualitative and can be readily adaptable to instrumental quantitation (col.1 lines 28-61).

It should be noted that the recitation an agglutination immunoassay or a method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535

F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Accordingly, it would have been obvious at the time of applicants invention to modify the method of Thomas et al., who teach methods for binding a nucleic acid to a polypeptide, fixing the nucleic acid bound polypeptide on the surface of a particle; contacting the antigen with an antibody and detecting the resultant antigen-antibody complex the modification including detection by agglutination immunoassay. No more than routine skill would have been required to perform the agglutination assay since Thomas et al., teach specific binding to polymer particles and measurement of the amount of reporter associated with the particle while Gibbons teaches binding antigens and antibodies and complementary nucleic acid strands bound to agglutinating agents to use well known agglutination techniques to detect antibody. One would have a reasonable expectation of success in modifying the method of Thomas et al., since agglutination assays do not require expensive detection equipment; agglutination assays can be readily adaptable to instrumental quantitation.

6. In response to applicants statements that Thomas et al., teach an additional polymerization step that the instant invention does not include or require. It is noted that the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of

art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.,* 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). See also M.P.E.P. 2111.03. Thus, applicant's argument fails to be persuasive, since the claim does not exclude additional polymerization steps applicants' arguments are not persuasive.

In response to applicant's arguments, the recitation of increasing the ability of the antigen to bond with the corresponding antibody results from the agglutination has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). There are no steps recited within the body of claim 33 that recite a specific structure-function relationship resulting in this increase of binding ability. Therefore, the structures of the prior art meet the limitation of the claims.

Since the Patent Office does not have the facilities for examining and comparing applicants' peptide with the peptide of the prior art reference, the burden is upon the

applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed peptide of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
March 4, 2004

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